# EXHIBIT S

Declaration of Lisa Davies, Executive Director of the Healthcare Facility Regulation Division of the Georgia Department of Community Health

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF TENNESSEEE**
**KNOXVILLE DIVISION**

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| STATES OF TENNESSEE, ALABAMA, ARKANSAS, GEORGIA, IDAHO, INDIANA, IOWA, LOUISIANA, MONTANA, NEBRASKA, NORTH DAKOTA, OHIO, SOUTH CAROLINA, SOUTH DAKOTA, and WEST VIRGINIA,<br><br>*Plaintiffs*,<br><br>v.<br><br>U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF CIVIL RIGHTS,<br><br>*Defendants.* | Civil Action No. 25-cv-00025 |

**DECLARATION OF LISA DAVIES**

Pursuant to 28 U.S.C. § 1746, I, **LISA DAVIES**, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as Executive Director of the Healthcare Facility Regulation Division (HFRD) of the Georgia Department of Community Health. HFRD is the State Survey Agency for Georgia under agreement with the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS") pursuant to Section 1864 of the Social Security Act. As such, HFRD is responsible for inspecting health care facilities, including but not limited to hospitals, nursing homes, dialysis centers, home health agencies, hospices and ambulatory surgery

centers, to ensure compliance with the minimum health and safety standards applicable to providers and suppliers participating in the Medicare and Medicaid programs pursuant to Titles 18 and 19 of the Social Security Act and accompanying federal regulations. HFRD also licenses and regulates over 30,000 healthcare facilities pursuant to state laws and regulations (*see* O.C.G.A. §§ 26-5-1 et seq.; 31-7-1 et seq.; 37-3-200 et seq. and 49-6-80 et seq.).

3. As part of my responsibilities, I oversee survey activities for over 100 field surveyors who conduct on-site inspections ("surveys") of healthcare facilities in Georgia every week; prepare survey reports, including but not limited to Statement of Deficiencies (CMS Form 2567); receive and review corrective action plans filed by healthcare facilities; and transfer cases to CMS with recommendation for federal enforcement actions and/or issue adverse action letters to impose state sanctions on non-compliant facilities that pose potential risk to patients and residents. These surveys include investigations of complaint allegations received from patients and their family members, as well as comprehensive licensure, certification or recertification surveys, and are conducted at entities covered under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) ("HIPAA").

4. The survey process requires a review of relevant medical records, including protected health information ("PHI"), to substantiate allegations of noncompliance or conduct routine reviews of critical safety protocols (e.g., maintaining timely documentation of patient vital signs and medication administration, obtaining patient consent for surgery, conducting appropriate triage and stabilization of emergency room patients, etc.). Evidence compiled by the state surveyor relating to violations of federal conditions of participation, such as patient or resident abuse or neglect, or violations of the Emergency Medical Treatment and Labor Act (EMTALA), must be submitted to CMS along with the Statement of Deficiencies. In EMTALA cases, the state agency

has only ten working days from the survey exit date to transmit all documentation to the CMS Regional Office for review (*see* Chapter 5, Section 5450, Medicare State Operations Manual "SOM", Complaint Procedures).

5. In cases involving serious physical harm, abuse or death, known as "immediate jeopardy" situations, the state agency must initiate the onsite inspection within two to three business days. Once onsite, if the state agency identifies an immediate jeopardy situation in a long-term care facility, for example, the facility's enrollment in Medicare and Medicaid is automatically terminated within twenty-three days of the survey exit date (*see* Chapter 7, Section 7301.1, SOM). This requires immediate exchange of all relevant documentation between the state agency and CMS. If the facility cannot abate the immediate jeopardy findings within this short time period, CMS terminates payments to the facility and all residents supported by those payments, most of whom are elderly and medically unstable, must be relocated. There is no mechanism under federal law for any extension of this enforcement remedy. Due to these short timeframes and the potentially catastrophic consequences of the investigation findings, it is imperative for the state agency to receive relevant medical records as expeditiously as possible.

6. I am aware of the Department of Health and Human Services' *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the "Final Rule"), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024, *id.* at 32,976.

7. The Final Rule has created barriers to the survey process, impeding the ability of our agency to complete thorough and timely investigations at healthcare facilities.

8. Under the Final Rule, healthcare facilities, including hospitals and nursing homes, are requiring that state surveyors sign an attestation that the information contained in the requested

medical records, if "potentially related" to "reproductive health care", is not sought for a purpose prohibited by the Final Rule. *See* 45 C.F.R. § 164.509(a).

9. These attestations reference potential criminal penalties, and must be signed by the field surveyor, who does not have a legal background, but instead is a nurse or other healthcare worker trained to conduct health and safety inspections. The interruption of the investigatory process to assess the ends and bases of an early-stage investigation, review legal documents, and, if needed, consult with an agency attorney, results in unnecessary delay in the completion of the survey and, thus, in the healthcare facility's response with the corrective action that may be needed to safeguard patients and residents in care. In cases where the allegation is rape or sexual abuse, or other forms of immediate jeopardy, delays in the investigation that may substantiate serious allegations could have far reaching consequences as the state agency also may need to refer matters to local law enforcement, professional licensing boards or other appropriate agencies for immediate action.

10. The Final Rule places the power to assess the validity of an attestation entirely with the covered entity to which the request is made. So, even after making an attestation it does not necessarily follow that the requesting party will receive the requested information. This means that in some cases the entity under investigation will have a veto on the investigators' ability to obtain records necessary for their investigation. As a result, HFRD has had to expend time and resources considering whether and how it will respond in cases when a covered entity refuses to provide requested information. Additionally, CMS has put state agencies on notice that failure to conduct complete surveys and investigations may impact the federal funding that the state agency receives for such purpose. (*see* QSO-22-12-ALL).

11. Thus, the Final Rule is impacting the public health and safety of patients and residents in Georgia healthcare facilities by delaying, impeding, and deterring critical, time-sensitive surveys and investigations.

Lisa Davies Digitally signed by Lisa Davies Date: 2025.03.31 14:42:05 -04'00'

Lisa Davies
Executive Director
Healthcare Facility Regulation Division
Georgia Department of Community Health

Date: March 31, 2025